



The Honorable Meena Seshamani, M.D., Ph.D.  
Deputy Administrator and Director  
The Center for Medicare  
7500 Security Blvd  
Baltimore, MD 21244

**RE: Medicare Drug Price Negotiation Program Guidance Memo**

Dear Dr. Seshamani,

On behalf of Patients Rising Now, thank you for allowing comments regarding the Centers for Medicare and Medicaid Services' (CMS) implementation of the Medicare Drug Price Negotiation Program provisions of the Inflation Reduction Act (IRA). Congress failed to make this law patient-centered, but CMS can still place the voice of the seniors the Agency serves first in drug pricing decisions and the law's implementation.

Formed in 2015, Patients Rising Now has developed a significant following of over 110,000 patients and caregivers and has guided them on their journeys to advocate for themselves and their loved ones to get the care and treatments they need to live a fulfilling life. As a patient advocacy organization, PRN supports reforms and legislation aimed at advancing patient access to affordable, quality healthcare.

While nothing in the Inflation Reduction Act requires a patient-centered approach, it is important that CMS understand that it is the patient that has the best understanding of what constitutes value when assessing a medicine. It is critical for seniors that CMS not follow the flawed model of organizations like the Institute for Clinical and Economic Review (ICER), which simulate cost-effectiveness from the payer's perspective. Patients frequently experience benefits from a therapy that are not captured by the health system. ICER's generalized, unscientific, and assumption-based models do not capture patient experience with any individual treatment. Patient engagement should be at the core of the IRA implementation and any decision on drug pricing. Relying on a small cadre of health economists, academics, and bureaucrats will create a narrow perspective that is evident in the initial guidance memo from CMS. How CMS is considering drugs based on unmet medical need is far too limited and unsophisticated.

Per the initial guidance memo, CMS "...intends to define [unmet medical need] as treating a disease or condition in cases where very limited or no other treatment options exist." This definition, as written, is shortsighted and increases the probability for misapplication or politicization of the term unmet medical need for diseases and their respective treatments in the future. This goes beyond a matter of semantics. A definition such as this will inform CMS' decisions on and interpretation of the IRA in the years to come. To that end, it is important that CMS amends this definition to be more in line with existing definitions of unmet medical need, not the least of which being the definition in the IRA: the very law that this guidance memo is seeking to implement.

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The FDA, as part of its Guidance for Industry on Expedited Programs for Serious Conditions – Drugs and Biologics (section III, subsection C), defines unmet medical as “...a condition whose treatment or diagnosis is not addressed adequately by available therapy.” This definition is far more comprehensive, more accurately reflects the healthcare landscape for many rare & chronic disease patients, and it creates more potential for better treatments to find their way to the patients who need them most. The definition of unmet medical need, as stated in the IRA, is nearly identical to the FDA definition, so any Agency action on this law must be more in keeping with the bill text.

In the guidance memo, we are pleased to see that the quality-adjusted life year (QALY) will not be used in the negotiation process. However, that is the extent of the prohibition. It does not extend to other areas of CMS such as Medicaid and the Children’s Health Insurance Program, both of which have been known to utilize the QALY in coverage and reimbursement decisions. The QALY is highly subjective and notorious because it discounts the lives of the elderly, the disabled and others who cannot achieve maximum QALY scores - and, thus, will never achieve the highest “quality of life. Given that the QALY is inherently discriminatory against rare disease patients, chronic disease patients, disabled patients, and seniors, its use in Federal and State health programs should be prohibited across the board. While it is encouraging that the new Negotiation Program will not allow QALYs, Patients Rising Now would like to see a similar ban for the rest of the Agency’s activities.

Solicitation of public comments on matters such as these are a critical aspect of Agency function and ensure any actions taken aren’t in direct contrast with the public and relevant stakeholders. In this guidance memo, CMS expresses the intention to solicit public comments on numerous facets of this complex law. However, in reference to section 30 of this memo (the implementation of the Negotiation Program for years 2026, 2027, and 2028), CMS not only declines to permit the customary notice-and-comment period but cites it as “...impractical, unnecessary, and contrary to the public interest.”

We understand that Congress did not craft the IRA as a patient-centric law, but excluding patient engagement is wrong. The drug price negotiation provisions of the IRA are unquestionably the most important part of the IRA and represent the most sweeping changes to Medicare since the implementation of Part D. Unilateral measures such as this are troubling to say the least and do not bode well for Agency implementation of Congressionally passed legislation in the future.

To that end, CMS must adopt a patients-first culture, where all decisions begin and end with their interest in mind. It is imperative that CMS develop clear, transparent processes for making decisions that are patient-centered and promote collaboration with patients in the decision-making processes. CMS must support the use of value-based coverage recommendations driven by the clinical value of the treatments, patient input, and real-world evidence. How patient experience and related data are quantitatively applied in the determination of a drug’s value and price in Medicare should always be publicly disclosed.

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Thank you again for holding a comment period on implementation of the IRA. These recommendations and others would not be possible without dedicated and frequent comment periods. Solicitation of comments from the public and relevant stakeholders is key to Agency making sound and informed decisions. And it is of the utmost importance that it continues so no missteps or unintended consequences occur as key provisions of this law take effect.

Sincerely,



Rachel Derby  
Executive Director